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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,379	11/28/2000	Hong Jin	7682-055-999	9862
20583	7590	01/28/2004		
JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017			EXAMINER LUCAS, ZACHARIAH	
			ART UNIT 1648	PAPER NUMBER

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/724,379

Applicant(s)

JIN ET AL.

Examiner

Zachariah Lucas

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1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 7-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 7-18 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-15, drawn to polynucleotides comprising paramyxovirus genomes that have been modified through the insertion of a heterologous sequence, classified in class 536, subclass 23.72.
  - II. Claims 12-15, drawn to polynucleotides comprising paramyxovirus genomes that have been modified by a mutation (other than insertion of a heterologous sequence) to the genome sequence, classified in class 536, subclass 23.72.
  - III. Claims 16-18, drawn to methods of making recombinant paramyxovirus comprising a genome modified through the insertion of a heterologous sequence by providing such a genome, and polynucleotides encoding the N, P, and L genes to the virus to a host cell, classified in class 435, subclass 69.1.
  - IV. Claims 16-18, drawn to methods of making recombinant paramyxovirus comprising a genome modified by a mutation to the genomic sequence by providing such a genome, and polynucleotides encoding the N, P, and L genes to the virus to a host cell, classified in class 435, subclass 69.1.

**For each of Groups I-IV above**, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-IV, and, election is also required to one of inventions (A)- (B). The inventions of subgroups (A) and (B) represent the elected invention wherein the viral genome is from (A) a respiratory syncytial virus (RSV), or (B) a parainfluenza virus (PIV).

**For Group I above**, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-IV, and, if Group I is elected, then election is

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also required to one of inventions (i)- (ii). The inventions of subgroups (i) and (ii) represent the elected invention wherein the heterologous sequence is from (i) a RSV, or (ii) a PIV.

It is further noted that, if additional claims dependant on claims 16-18 are added that reflect the limitations described in claims 10 and 11 with respect to claim 7, then further election of one of subgroups (i) and (ii) will also be required if the Applicant elects Group III.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of subgroups (A) and (B), and of subgroups (i) and (ii) are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, subgroup (A) represents a structurally distinct polynucleotide from the inventions of subgroup (B). Each of these subgroups encodes for a different virus, and thus they perform different functions and would have different effects when expressed. The inventions of subgroups (i) and (ii) are distinct for substantially the same reasons as subgroups (A) and (B).

3. The inventions of Groups I and II, and the inventions of Groups III and IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. See MPEP § 806.05(d). In the instant case, invention the inventions of Groups I and III have separate utilities from, respectively, the inventions of Groups II and IV because either of the polynucleotides of Group I or II, or the methods of Group III or IV may be used in the creation of an attenuated paramyxovirus particle. Because the inventions are separately usable, they are distinct.

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4. The inventions of Groups I and II are related as product and processes of use with the inventions of Groups III and IV. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides of Groups I and II may be used in other process than for the making of recombinant virus. They may also be used in hybridization assays for the detection of RSV infection. The inventions are therefore distinct. .

### ***Conclusion***

5. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

6. It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn. Claims 7 and 12 are considered to be a linking claim to Groups I and II, to subgroups (A) and (B), and to

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subgroups (i) and (ii). Claim 16 is considered to be a linking claim as to Groups III and IV, and to subgroups (A) and (B).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.


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8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Z. Lucas  
Patent Examiner

  
JAMES HOUSEL 1/24/04  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1000